DETAILED ACTION

Interview Summary

Applicant's representative, Dr. John McDonald, telephoned the Examiner on the week of 11 July 2010, to inform the Examiner that the restriction was performed on the wrong claims, and that an amend was provided on 4 March 2002. The Examiner telephoned Dr. McDonald and informed him that a revised restriction requirement would be sent.

The claim set, provided 16 March 2010, was actually a claim set provided from the international bureau, or a copy of the international bureau's documents provided by Applicant to establish a request for revival. It is difficult to tell, but it is clear that it is not meant to amend the claims as filed. Therefore, the claim set which is presently pending is the claim set of 3/4/02.

The Restriction Requirement of 7 July 2010 is hereby withdrawn in favor of the present Restriction Requirement.

Claims 42-69 are presently pending as filed in the preliminary amendment of 3/4/02 and subject to the following restriction and/or species elections requirements.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 43-46, 55, 59, and 60-63, drawn to a bacterial ghost comprising a Markush group of active substance generas.

Group II, claim(s) 47, 48, 51, and 54, drawn to a bacterial ghost comprising an active substance and the composition further comprising a receptor.

Group III, claim(s) 49, 50, and 52, drawn to a bacterial ghost comprising an active substance and the composition further comprising a fusion protein.

Group IV, claim(s) 53, drawn to a bacterial ghost comprising an active substance, which bacterial ghost is derived from a gram negative or gram positive bacterium.

Group V, claim(s) 56 or 57, drawn to a bacterial ghost comprising an active substance, the ghost further comprising a matrix inside the ghost.

Group VI, claim(s) 58, drawn to a bacterial ghost comprising an active substance, further comprising a target-specific surface molecule located on an outer surface of the ghost.

Group VII, claim(s) 64 and 66, drawn to a method of treating or preventing disease in an animal, comprising administration of the composition of Claim 42 to the animal.

Group VIII, claim(s) 65, drawn to a method of vaccination of an animal, comprising administration of the composition of Claim 42 to the animal.

Group IX, claim(s) 68, drawn to a method of making a bacterial ghost of Claim 42, comprising providing bacterial ghosts, and contacting the ghosts with an active substance under conditions which permit the packaging of the active substance.

Group X, claim(s) 69, drawn to a method of delivering a substance to a desired location comprising providing the composition of Claim 42 to the location.

Group XI, claim(s) 67, drawn to a method of providing gene therapy to an animal, comprising administration of the composition of Claim 55 to the animal.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature shared between any two groups is a bacterial ghost comprising an active substance. Applicant's provided reference: Szostak, et al. (1996) Journal of Biotechnology, 44: 161-170, provides evidence of several previously known and instantly-disclosed-in-the-reference bacterial ghosts containing active substance(s). Hence, the special technical feature is taught in the prior Art. In addition, the ghosts may be used for distinct purposes, like studying membrane physiology, the processes of making can be performed by distinct methods as evidenced by the dependency of original claim 40, and ghosts of similar structure were known to exist prior to Applicant's disclosure: eukaryotic minicells have been utilized for years prior to Applicant's disclosure to study physiology. Lastly, each of the ghosts may be used in separate methods reasons of administration, as evidenced by the uses of treatment of disease, vaccination, and gene therapy, and general tool for science for delivery; and the method of making may be had by exposing the bacterium to the active substance, then forming ghosts. Hence, because of the distinct structure, providing distinct function, in each group, it would pose a serious burden on the Examiner to search and consider any two inventions together, and such demonstrates a lack of general inventive concept at the same time.

Claim 42 link(s) inventions I-VI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 42. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections

over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicant should choose Invention I:

Applicant is required to choose a specific active substance from the generas listed in Claims 43-46, 55, 59, and 60-63, as well as a specific species of such substance (i.e., non-generic in structure) as further supported by the specification. I.e., choice of a nucleic acid is not good, because it encompasses DNA, RNA, and many other forms of nucleic acid, and further a choice of the structure of such DNA, RNA, or other form is required, as supported by the specification.

If Applicant should choose Invention II:

Applicant is required to choose whether the receptor is located on the inside of the plasma membrane or is a non-integral membrane component, as in Claim 48;

Applicant is required to choose a specific receptor as listed in Claim 48, and further supported by the specification;

Applicant is required to choose whether the active substance is immobilized through direct or indirect interactions with the receptor, as in claim 51; and

Applicant is required to choose a specific substance which can bind the active substance, as supported by the specification, and claimed in Claim 54.

If Applicant should choose Invention III:

Applicant is required to choose a specific fusion protein, its domains, and whether streptavidin/avidin is the receptor domain, as elucidated in Claims 49, 50, and 52, and as further supported by the specification.

If Applicant should choose Invention IV:

Applicant should choose gram negative or gram positive bacterium, as listed in Claim 53.

If Applicant should choose Invention V:

Applicant should choose a specific matrix structure as listed in Claims 56-57, and as specifically supported by the specification.

If Applicant should choose Invention VI:

Applicant is required to choose a specific target specific surface molecule located on the outer surface of the bacterial ghost, as listed in Claim 58 and supported by the specification.

If Applicant should choose Invention VII:

Applicant is required to choose a specific structure for the composition which is administered, as listed in the genera of substances encompassed by Claim 64, and as supported by the specification.

If Applicant should choose Invention VIII:

Applicant is required to choose a specific structure for the composition which is administered, as listed in the genera of substances encompassed by Claim 65, and as supported by the specification.

If Applicant should choose Invention IX:

Applicant is required to choose a specific bacterial ghost, active substance, and conditions which permit packaging, as listed in Claim 68 and as specifically supported by the specification.

If Applicant should choose Invention X:

Applicant is required to choose a specific structure for the composition which is administered, as listed in the genera of substances encompassed by Claim 69, and as supported by the specification.

If Applicant should choose Invention XI:

Applicant is required to choose a specific structure for the nucleic acid which is administered, as listed in the genera of nucleic acids encompassed by Claim 67, and as supported by the specification.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: all claims are generic in some aspect of species election provided above.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage

application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633